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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/724,406	11/28/2000	Joseph A. Francisco	9632-006-999	7578

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EXAMINER	
YU, MISOOK	

ART UNIT	PAPER NUMBER
1642	

DATE MAILED: 04/01/2004

Please find below and/or attached an Office communication concerning this application or proceeding.

Advisory Action	Application No.	Applicant(s)	
	09/724,406	FRANCISCO ET AL.	
	Examiner	Art Unit	
	MISOOK YU, Ph.D.	1642	

--The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

THE REPLY FILED 15 March 2004 FAILS TO PLACE THIS APPLICATION IN CONDITION FOR ALLOWANCE. Therefore, further action by the applicant is required to avoid abandonment of this application. A proper reply to a final rejection under 37 CFR 1.113 may only be either: (1) a timely filed amendment which places the application in condition for allowance; (2) a timely filed Notice of Appeal (with appeal fee); or (3) a timely filed Request for Continued Examination (RCE) in compliance with 37 CFR 1.114.

PERIOD FOR REPLY [check either a) or b)]

a) ☒ The period for reply expires 3 months from the mailing date of the final rejection.

b) ☐ The period for reply expires on: (1) the mailing date of this Advisory Action, or (2) the date set forth in the final rejection, whichever is later. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of the final rejection. ONLY CHECK THIS BOX WHEN THE FIRST REPLY WAS FILED WITHIN TWO MONTHS OF THE FINAL REJECTION. See MPEP 706.07(f).

Extensions of time may be obtained under 37 CFR 1.136(a). The date on which the petition under 37 CFR 1.136(a) and the appropriate extension fee have been filed is the date for purposes of determining the period of extension and the corresponding amount of the fee. The appropriate extension fee under 37 CFR 1.17(a) is calculated from: (1) the expiration date of the shortened statutory period for reply originally set in the final Office action; or (2) as set forth in (b) above, if checked. Any reply received by the Office later than three months after the mailing date of the final rejection, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

1. ☐ A Notice of Appeal was filed on _____. Appellant's Brief must be filed within the period set forth in 37 CFR 1.192(a), or any extension thereof (37 CFR 1.191(d)), to avoid dismissal of the appeal.

2. ☒ The proposed amendment(s) will not be entered because:

   (a) ☒ they raise new issues that would require further consideration and/or search (see NOTE below);

   (b) ☐ they raise the issue of new matter (see Note below);

   (c) ☐ they are not deemed to place the application in better form for appeal by materially reducing or simplifying the issues for appeal; and/or

   (d) ☐ they present additional claims without canceling a corresponding number of finally rejected claims.

   NOTE: *See Continuation Sheet*.

3. ☒ Applicant's reply has overcome the following rejection(s): None.

4. ☐ Newly proposed or amended claim(s) _____ would be allowable if submitted in a separate, timely filed amendment canceling the non-allowable claim(s).

5. ☒ The a)☐ affidavit, b)☐ exhibit, or c)☒ request for reconsideration has been considered but does NOT place the application in condition for allowance because: *See Continuation Sheet*.

6. ☐ The affidavit or exhibit will NOT be considered because it is not directed SOLELY to issues which were newly raised by the Examiner in the final rejection.

7. ☒ For purposes of Appeal, the proposed amendment(s) a)☒ will not be entered or b)☐ will be entered and an explanation of how the new or amended claims would be rejected is provided below or appended.

   The status of the claim(s) is (or will be) as follows:

   Claim(s) allowed: _____.

   Claim(s) objected to: _____.

   Claim(s) rejected: *1-8,11,13-19 and 67*.

   Claim(s) withdrawn from consideration: _____.

8. ☐ The drawing correction filed on _____ is a)☐ approved or b)☐ disapproved by the Examiner.

9. ☐ Note the attached Information Disclosure Statement(s)(PTO-1449) Paper No(s). _____.

10. ☐ Other: _____

Misook Yu, 3/30/2004

Continuation of 2. NOTE: They raises new issues i.e. 112 First and Second Paragraphs issues that requires for further consideration. The amended claim 67 now seems to have only one culture condition but the last line of step comparison step. It is not clear what is being compared with. The deleted limitation "only" appears to have some meaning as to what is added in test samples and what is not added in control sample. Also the amended claim 67 several steps with 2 (C), the last one should be (E).

Continuation of 5. does NOT place the application in condition for allowance because: Claims 1-8, 11, 13-19, and 67 remain rejected for reason of record.

Applicant argues that Lemke is not 102 (b) art because: Lemke does not teach the instantly claimed limitation "exerts cytostatic or cytotoxic effect on the Hodgkin's cell line" and Lemke discloses Ki-4 as an exemplary antibody; Lemke does not discloses any data showing unconjuated anti-CD30 antibody can treat Hodgkin's disease; Lemke fairly teaches an antibody that does not promote the release of soluble CD30.

These arguments have been fully considered but found unpersuasive because Lemke teaches treatment of Hodgkin's disease using a generic anti-CD antibody (without any toxin attached) that releases soluble CD30 from Hodgkin's disease cells to an amount of less than 10 % at the abstract and claims 13 and 14. Further, Lemke teaches HeFi-1 and C10 (a.k.a. AC10 according applicant's amendment at page 6, line 5 of 21st paragraph filed on 10/02/2003) at Table 2. Thus, the Lemke teaches that any generic antibody to CD30 could be used to treat Hodgkin's disease as long as said antibody releases soluble CD30 from Hodgkin's disease cells to an amount of less than 10 %.

Applicant argues that Ber-H2 does not have the instantly recited function as taught by Engert et al, thus fulfilling the Office's invitation to present scientific data that HeFi-1 and C10 disclosed at Table II at page 21 of Lemke release more than 10 % soluble CD30. These argument has been fully considered but found unpersuasive because Engert et al do not present any scientific evidence that HeFi-1 and C10 disclosed at Table II at page 21 of Lemke do not possess the functional characteristics disclosed in claim 1 of Lemke. The Office does not have the facilities and resources to provide the factual evidence needed in order to establish that the composition of the prior art does not possess the same material, structural and functional characteristics of the instantly claimed composition. In the absence of evidence to the contrary, the burden is on the applicant to prove that the claimed antibody is different from those taught by Lemke and to establish patentable differences. See In re Best 562F.2d 1252, 195 USPQ 430 (CCPA 1977) and Ex parte Gray 10 USPQ 2d 1922 (PTO Bd. Pat. App. & Int. 1989).

Applicant further argues that Lemke does not anticipates claim 11 because Lemke teaches Cluster A antibodies are useful and AC 1 falls into Cluster C. These argument has been fully considered but found unpersuasive because Lemke does not limit Cluster A in claim 1 of Lemke as having the activity. The instant specification at page 29 lines 28-29 says that instant SEQ ID NO:2 is variable region of AC10 (a.k.a. C10) disclosed Table 2 at page 21 of the art. Therefore, the C10 antibody is a protein comprises an amino acid sequence that has SEQ ID NO:2, thus Lemke anticipates claim 11.

LARRY R. HELMS, PH.D
PRIMARY EXAMINER